DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration
10903 New Hampshire Avenue
Document Control Center – WO66-G609
Silver Spring, MD 20993-0002

October 15, 2014

OBERON GmbH Fiber Technologies
% Dr. Armin Kaus
MED-Fibers Incorporated
7404 West Detroit Street, Suite 140
Chandler, Arizona 85226

Re: K140470
Trade Name: OBERON Laser Surgery Fiber
Regulation Number: 21 CFR 878.4810
Regulation Name: Laser surgical instrument for use in general and plastic surgery and in dermatology
Regulatory Class: Class II
Product Code: GEX
Dated: September 12, 2014
Received: September 17, 2014

Dear Dr. Kaus:

We have reviewed your Section 510(k) premarket notification of intent to market the device referenced above and have determined the device is substantially equivalent (for the indications for use stated in the enclosure) to legally marketed predicate devices marketed in interstate commerce prior to May 28, 1976, the enactment date of the Medical Device Amendments, or to devices that have been reclassified in accordance with the provisions of the Federal Food, Drug, and Cosmetic Act (Act) that do not require approval of a premarket approval application (PMA). You may, therefore, market the device, subject to the general controls provisions of the Act. The general controls provisions of the Act include requirements for annual registration, listing of devices, good manufacturing practice, labeling, and prohibitions against misbranding and adulteration. Please note: CDRH does not evaluate information related to contract liability warranties. We remind you; however, that device labeling must be truthful and not misleading.

If your device is classified (see above) into either class II (Special Controls) or class III (PMA), it may be subject to additional controls. Existing major regulations affecting your device can be found in the Code of Federal Regulations, Title 21, Parts 800 to 898. In addition, FDA may publish further announcements concerning your device in the Federal Register.

Please be advised that FDA's issuance of a substantial equivalence determination does not mean that FDA has made a determination that your device complies with other requirements of the Act or any Federal statutes and regulations administered by other Federal agencies. You must comply with all the Act's requirements, including, but not limited to: registration and listing (21

CFR Part 807); labeling (21 CFR Part 801); medical device reporting (reporting of medical device-related adverse events) (21 CFR 803); good manufacturing practice requirements as set forth in the quality systems (QS) regulation (21 CFR Part 820); and if applicable, the electronic product radiation control provisions (Sections 531-542 of the Act); 21 CFR 1000-1050.

If you desire specific advice for your device on our labeling regulation (21 CFR Part 801), please contact the Division of Small Manufacturers, International and Consumer Assistance at its toll-free number (800) 638-2041 or (301) 796-7100 or at its Internet address http://www.fda.gov/MedicalDevices/ResourcesforYou/Industry/default.htm. Also, please note the regulation entitled, "Misbranding by reference to premarket notification" (21CFR Part 807.97). For questions regarding the reporting of adverse events under the MDR regulation (21 CFR Part 803), please go to http://www.fda.gov/MedicalDevices/Safety/ReportaProblem/default.htm for the CDRH's Office of Surveillance and Biometrics/Division of Postmarket Surveillance.

You may obtain other general information on your responsibilities under the Act from the Division of Small Manufacturers, International and Consumer Assistance at its toll-free number (800) 638-2041 or (301) 796-7100 or at its Internet address http://www.fda.gov/MedicalDevices/ResourcesforYou/Industry/default.htm.

Sincerely yours,

Binita S. Ashar -S
2014.10.15 15:29:03 -04'00'

Binita S. Ashar, M.D., M.B.A., F.A.C.S.
Director
Division of Surgical Devices
Office of Device Evaluation
Center for Devices and
Radiological Health

Enclosure

DEPARTMENT OF HEALTH AND HUMAN SERVICES
Food and Drug Administration

Indications for Use

Form Approved: OMB No. 0910-0120
Expiration Date: January 31, 2017
See PRA Statement below.

510(k) Number *(if known)*
K140470

Device Name
OBERON Laser Surgery Fiber

Indications for Use *(Describe)*
The OBERON, laser surgery fiber, Side Fire laser surgery fibers are intended for delivery of laser light to soft tissue in the contact and non-contact mode during surgical procedures including via endoscopes and cystoscopes. The OBERON laser surgery fiber is intended for use with any cleared surgical laser with a SMA 905 connector. The OBERON laser surgery fibers are indicated for use in general surgery applications for: incision, excision, vaporization, ablation, hemostasis or coagulation of soft tissue in a contact or non contact mode. It is also indicated for use in open or closed endoscopic applications where incision, excision, tissue dissection, excision of external tumors and lesions, complete or partial resection of internal organs, tumors or lesions, tissue vaporization, hemostasis and or coagulation may be indicated. (Diode Laser 532nm- 2100nm) OBERON laser surgery fiber is also indicated for use in lithotripsy with a compatible laser cleared for the desired application. It is indicated for use with Argon, KTP/532, Ho;YAG, Nd;YAG, 1.44YAG and Diode Lasers (532nm - 2100nm) with peak and continuous power from 1-100 Watt. OBERON laser surgery fibers are indicated for use in general surgery, urology, gastroenterology, gynecology, dermatology, vascular surgery, neurosurgery, plastic surgery, ENT and endovenous occlusion of the greater saphenous vein in the patient with superficial vein reflux and laser assisted lipolysis with an approved compatible laser marketed for use in the desired application.

Type of Use *(Select one or both, as applicable)*

☒ Prescription Use (Part 21 CFR 801 Subpart D) ☐ Over-The-Counter Use (21 CFR 801 Subpart C)

PLEASE DO NOT WRITE BELOW THIS LINE – CONTINUE ON A SEPARATE PAGE IF NEEDED.

FOR FDA USE ONLY

Concurrence of Center for Devices and Radiological Health (CDRH) *(Signature)*

510 (k) SUMMARY

This 510(k) summary of safety and effectiveness is submitted in accordance with all of the requirements and follows Office of Device Evaluation guidance concerning the organization of a 510 (k) summary.

OBERON 's Laser Surgery Fiber

Submitter's Name, Address, Telephone Number, Contact Person and Date Prepared

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Official Correspondent:
Dr. Armin Kaus, Ph.D.
7404 W. Detroit Street, STE 140
Chandler, AZ 85226

Date Prepared: October 7, 2014

Name of Device and Name of Sponsor

OBERON Laser Surgery Fiber

OBERON GmbH Fiber Technologies
Freiheitsstrasse 120
15745 Wildau, GERMANY

Common or Usual Name

Nd:YAG-, Ho:YAG-, KTP- and Diode Laser – Laser Fiber Delivery Systems

Classification Name

Surgical Laser Accessory
Regulation: 21 CFR §878.4810
Classification: II
Product Code: GEX

Predicate Devices

1 - Per 21 CFR 807.92 item (6) Summary with comparison values

	OBERON GmbH	**MED-Fibers, Inc.**	**Fiberoptic Fab**
		K124003	K120810
Intended use	The fiber optic laser delivery devices are intended for delivery of laser light to soft tissue in the contact and noncontact mode during surgical procedures including via endoscopes and cystoscopes. The laser fiber is intended for use with any cleared surgical laser with an SMA 905 and compatible connectors.	The surgical fiber optic Laser delivery devices are intended for delivery of laser light to soft tissue in the contact and non contact mode during surgical procedures. The delivery device is intended for use with any surgical lasers with cleared laser with a compatible SMA 905 and compatible connectors.	The fiber optic laser delivery system is intended for delivery of laser light to soft tissue in the contact and non contact mode during surgical procedures. The fiber optic delivery System is intended for use with any cleared surgical laser with an SMA 905.
Delivery Systems			
Fiber	Flexible Fiber	Flexible Fiber	Flexible Fiber
Material	Quartz Glass	Quartz Glass	Quartz Glass
Core Diameter	200 – 600 micron	200 – 1000 micron	200 – 1000 micron
Proximal end	SMA 905 and other compatible connectors	SMA 905 and other compatible connectors	SMA 905, SMA 906 and other compatible connectors
Distal end	flat, shaped, ball, round, side fire, radial	flat, side fire and different shapes	flat, shaped, side fire
Sterile (Yes/No)	Yes	Yes	Yes
Max Recommended Power	Core Size: 200, 272 µ 20 W 365 µ 40 W 500 µ 100 W 400, 600 µ HPCS 30 W 600 µIRHCN 100 W 800 and 1000µ N/A	up to 45 W up to 60 W up to 100 W up to 40 W up to 100 W up to 200W	up to 45 W up to 113 W N/A N/A up to 100 W up to 200 W
Indication for use	The laser delivery devices are intended for use in laser based surgical application to deliver the laser light to soft tissue during surgical applications. The delivery device is cleared for surgical lasers with compatible SMA 905 connectors. It is indicated for use in general surgery applications for incision, excision, vaporization, ablation and or coagulation. It is indicated for use in soft tissue procedures with cleared surgical laser systems with different wavelength. It is also indicated for use with cleared compatible laser systems in lithotripsy for the desired application.	The surgical fiber optic laser delivery devices, Endo-ENT fibers, side fire Fibers and Endo probes in the contact and non-contact mode during surgical procedures including via endoscopes and cysto-scopes. The surgical laser fiber is intended for use with any cleared surgical laser with an SMA 905 and compatible connectors. The surgical fibers are indicated for use in general surgery applications for incision, excision, vaporization, ablation, hemostasis, or coagulation. It is also indicated for use In open or closed endo- scopic applications where incision, excision, tissue dissection, excision of external tumors and lesions complete or partial resection of intern. organs, It is also intended as an aid for otology procedures. In addition all surgical devices are intended for use in lithotripsy applications with cleared laser Systems.	The fiber optic laser delivery system is indicated for use in general surgery applications for incision, excision vaporization, ablation, hemostasis or coagulation, of soft tissue in a contact or non-contact mode. It is also indicated for use in open or closed endoscopic applications, where incision, excision, tissue dissection, excision of external tumors or lesions, complete or partial resection of internal organs, tumors or lesions, tissue vaporization, hemostasis and or coagulation may be indicated. It is also indicated for use in lithotripsy with a compatible laser cleared for the desired application. Its intended to use for different cleared lasers with peak and continuous power from 1W – 200W.

Intended Use / Indications of Use

The OBERON's, laser surgery fiber, is intended for delivery of laser light to soft tissue in the contact and non-contact mode during surgical procedures including via endoscopes and cystoscopes. The OBERON laser surgery fiber is intended for use with any cleared surgical laser with a SMA 905 or compatible connectors.

The OBERON, laser surgery fibers, Side Fire Laser surgery fibers and Dental Probes are intended for delivery of laser light to soft tissue in the contact and non-contact mode during surgical procedures including via endoscopes and cystoscopes. The OBERON laser surgery fibers are intended for use with any cleared surgical laser with a SMA 905 connector. The OBERON laser surgery fibers laser are indicated for use in general surgery applications for: incision, excision, vaporization, ablation, hemostasis or coagulation of soft tissue in a contact or non contact mode. It is also indicated for use in open or closed endoscopic applications where incision, excision, tissue dissection, excision of external tumors and lesions, complete or partial resection of internal organs, tumors or lesions, tissue vaporization, hemostasis and or coagulation may be indicated. (Diode Laser 532nm – 2100nm) OBERON laser surgery fiber is also indicated for use in lithotripsy with a compatible laser cleared for the desired application. It is indicated for use with Argon, KTP/532, Ho;YAG, Nd;YAG, 1.44YAG and Diode Lasers (532nm – 2100nm) with peak and continuous power from 1 – 100 Watt. OBERON laser surgery fibers are indicated for use in general surgery, urology, gastroenterology, gynecology, dermatology,

vascular surgery, neurosurgery, plastic surgery, ENT and endovenous occlusion of the greater saphenous vein in the patient with superficial vein reflux and laser assisted lipolysis with an approved compatible laser marketed for use in the desired application.

Technical Characteristics

OBERON's laser surgery fiber contains the same components and the same technological characteristics as the predicate devices. The fiber core and cladding or fibers with no cladding are made from silica which is the same material used in all the predicate devices. As mentioned, the optical fiber is made out of silica with a coaxially mounted protective sheath. The fiber distal tip can be several configurations and the fiber can be also used with hand pieces.
OBERON's laser surgery fiber has no differences in technology and as such does not raise any new questions on safety or efficacy. Various core diameter sizes (200, 272, 365, 400, 550, 600microns) are offered.

Performance Data

The performance of the OBERON's laser surgery fiber is well established and documented so no performance testing is included. The OBERON's laser surgery fiber delivery system operates in the same manner as the predicate devices and performs with no difference as compared with the predicate devices.

Substantial Equivalence

The OBERON's laser surgery fibers are as safe and effective for the indications for use as the Laser Peripherals, Leoni, Lumenis, MED-Fibers, Cynosure, Fiberoptic Fabrications and CermaOptec fiber optic laser delivery systems previously cleared thus the OBERON's laser surgery fibers are substantially equivalent.

Signed:
Dr. Armin Kaus, Ph.D.
Official Correspondent